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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,608	01/18/2002	Tetsumasa Ito	027929.101-US00	4635

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COVINGTON & BURLING
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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,608	ITO, TETSUMASA	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) 13-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-12 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 22 September 2003 in which claims 1-5 and 9-12 were amended, claims 6-7 were canceled and claims 20-22 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 20 June 2003 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection necessitated by amendment are discussed.

Claims 1-5, 9-12 and 20-22 are under prosecution.

Claim Objections

2. Claims 11 and 12 are objected to because of the following informalities:

a. Claim 11 is objected to because subject-verb agreement in the phrase "probes is immobilized the plurality of electrodes" is incorrect and because the word "on" after "immobilized" has been deleted.

b. Claim 12 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claims (e.g. Claim 4) See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation "wherein the heat insulating member comprises a resin" is added to new Claim 20. However, the specification fails to define or provide any disclosure to support such claim recitation.

The specification teaches a heat insulating member and they specifically teach "The heat insulating member used to cover the electrode is preferably PEEK (polyether ether ketone) or PTFE (polytetrafluoroethylene)." But the specification does not teach or describe the newly claimed "resin". Therefore, the amendment introduces new matter into the specification.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE" (emphasis added).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1- 5, 10-12 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Yasuda et al (U.S. Patent No. 6,093,370, issued 25 July 2000).

Regarding Claim 1, Yasuda et al disclose a gene detection system comprising a probe-immobilizing support on which a probe is immobilized (Fig. 2, #14 and Fig. 10-11, #221) and heating and cooling means (Fig. 2, #31; Fig. 10-11, #225) disposed in contact with a location different from a surface of the probe-immobilizing support on which the probe is immobilized (Column 4, lines 54-67 and Column 10, line 56-Column 12, line 12) wherein the probes are immobilized on the electrode-supporting substrate (Column 11, lines 50-58, Fig. 11, #226) wherein the circumferential surface of the electrode is covered with a heat insulating member (i.e. at hatch-marked area of #132, labeled "c", Fig. 11).

Regarding Claim 2, Yasuda et al disclose the system wherein the heating and cooling means comprises a soaking component (i.e. thermally conductive insulating substrate #132) in contact with a surface opposite the probe-immobilizing support and a heating and cooling element disposed in contact with the soaking component (Column 11, lines 43-62 and Fig. 11).

Regarding Claim 3, Yasuda et al disclose the system where the thermal capacity of the soaking component is greater than the thermal capacity of the probe-immobilizing support i.e. the substrate #132 is an insulating substrate (Column 11, lines 43-62).

Regarding Claim 4, Yasuda et al disclose the system wherein the soaking component comprises a temperature sensor (i.e. thermosister, Fig. 11, #231 and temperature control unit,

Art Unit: 1634

Fig. 11, #133) for measuring temperature and controls the actuation of the heating and cooling element (Column 11, lines 43-62).

Regarding Claim 5, Yasuda et al disclose the system wherein the heating and cooling element consists of a Peltier element (Column 19, lines 5-24).

Regarding Claim 10, Yasuda et al disclose the system wherein the electrodes comprises a plurality of electrodes (Column 11, lines 43-62).

Regarding Claim 11, Yasuda et al disclose the system wherein the electrode substrate comprises a plurality of electrodes substrates supporting the plurality of electrodes and the heating and cooling means independently controls the temperature of each of the plurality of electrode substrates (Column 11, lines 7-23) and wherein the probes immobilized on the plurality of electrodes detect a predetermined sequence different from another probe i.e. a different sequence for each area (Column 4, lines 61-65).

Regarding Claim 12, Yasuda et al disclose a gene detection device comprising the gene detection system of Claim 1 and control means for controlling heating and cooling means (Column 10, line 56-Column 12, line 62 and Fig. 10-11).

Regarding Claim 22, Yasuda et al disclose the system wherein the heating and cooling means independently controls a temperature of each of the electrodes (Column 11, lines 7-14).

Response to Arguments

7. Applicant argues that Yasuda et al do not teach a thermally insulating substrate but in contrast teach the substrate is thermally conductive and cite (Column 11, lines 59-60). The argument has been considered but is not found persuasive because a thorough reading of the cited passage reveals that Yasuda et al teach their substrate is a "thermally conductive insulating substrate" (e.g. Column 11, lines 6-7, 45-46 and 59-60). Therefore, while Yasuda teach their substrate is conductive, they further teach the substrate is insulating. While it may seem contradictory that the substrate of Yasuda is thermally conductive and insulating,

Art Unit: 1634

such substrates are well known. For example, another thermally conductive insulating member illustrating the substrate of Yasuda is a home heating pad used to provide (conduct) heat to a specific area on a person's body. Older heating pad consisted of a rubber pouch for containing boiling water. This heating pad conducts heat, but the rubber material provides insulation to prevent the boiling water from contacting the body. Newer heating pads produce heat electrically, but are covered in materials such that heat is evolved by the body is insulated from direct contact with the heat source. These heating pads are obviously thermally conductive because they provide heat. The heating pads are also insulating because they prevent direct contact between the heat source and the body.

Because Yasuda et al specifically teach their substrate is a "thermally conductive insulating substrate", they teach the substrate is insulating. Therefore, Yasuda et al teach the device as claimed.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 9, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasuda et al (U.S. Patent No. 6,093,370, issued 25 July 2000) in view of Malmros et al (U.S. Patent No. 5,108,576, issued 28 April 1992).

Art Unit: 1634

Regarding Claim 9, 20 and 21, Yasuda et al disclose a gene detection system comprising a probe-immobilizing support on which a probe is immobilized (Fig. 2, #14 and Fig. 10-11, #221) and heating and cooling means (Fig. 2, #31; Fig. 10-11, #225) disposed in contact with a location different from a surface of the probe-immobilizing support on which the probe is immobilized (Column 4, lines 54-67 and Column 10, line 56-Column 12, line 12) wherein the probes are immobilized on the electrode-supporting substrate (Column 11, lines 50-58, Fig. 11, #226) wherein the circumferential surface of the electrode is covered with a heat insulating member (i.e. at hatch-marked area of #132, labeled "c", Fig. 11). Yasuda et al do not teach the electrode is equipped with a surface comprising gold, silver or copper (Claim 9) they are silent regarding the composition of the insulating member (Claim 20) and they do not teach the electrode is a pin (Claim 21). However, resin insulation covering a pin electrode wherein the electrode comprises silver were well known in the art at the time the claimed invention was made as taught by Malmros et al. (Abstract; Column 3, line 40-Column 4, line 24; and Example 2).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the electrodes of Yasuda et al by utilizing a matrix insulation on a pin electrode comprising silver of Malmros et al based on the differential immobilization of reactant taught by Malmros et al for the expected benefit of providing a uniformly coated differential sensor (Malmros et al, Column 1, lines 46-66).

Art Unit: 1634

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878 until 13 January 2004. Starting 14 January 2004, the examiner's phone number will be (517) 272-0741. The examiner can normally be reached on 6:00 TO 3:30 Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
December 15, 2003